

CALCIUM FOLIC ACID PLUS D CHEWABLE- cholecalciferol, magnesium, boron, folic acid, pyridoxine, cyanocobalamin wafer
Acella Pharmaceuticals, LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, [click here](#).

Calcium-Folic Acid Plus D Chewable

Wafers

Rx Only

Description: Calcium-Folic Acid Plus D Chewable Wafers are a chewable Calcium and Folic Acid Formula with Vitamin D, Magnesium and other nutrients for the maintenance and support of special dietary needs of any individual where supplementation with the ingredients contained within would prove beneficial including: premenopausal, menopausal and postmenopausal patients pertaining to the loss of calcium or calcium deficit, as well as cardiovascular wellness managed through dietary therapy.

SUPPLEMENT FACTS	
Each Wafer Contains :	
Calcium Carbonate (Elemental 500 mg)	1342 mg
Vitamin D ₃	300 IU
Magnesium	50 mg
Boron	250 mcg
Folic Acid	1 mg
Vitamin B ₆	10 mg
Vitamin B ₁₂	125 mcg

Other Ingredients: Fructose, Natural Cocoa Dutch Chocolate, Stearic Acid, Plasdone, Natural Chocolate Flavor, Magnesium Stearate, Acacia Gum, Silicon Dioxide.

Nutrition Information: Each wafer contains 11 calories and 2 grams of carbohydrates.

Indications and Usage: Calcium-Folic Acid Plus D Chewable Wafers are indicated, in addition to diet, to help satisfy the distinctive nutritional requirements of individuals under the supervision of a physician for the treatment of calcium deficiency, skeletal weakness and osteoporosis. Calcium-Folic Acid Plus D Chewable Wafers supplementation may be beneficial to individuals who have an insufficient dietary intake of the nutrients contained therein. Calcium and vitamin D supplementation may be useful in both preventing and treating osteoporosis. Vitamin D supplementation may be beneficial to those who are institutionalized and/or have reduced exposure to sunlight. Folic acid, vitamin B₆, and vitamin B₁₂, may help reduce the risk of cardiovascular disease by lowering blood levels of homocysteine. If dietary intake of calcium is inadequate, patients currently taking bisphosphonates for treatment of osteoporosis should be instructed to take calcium and vitamin D daily (Calcium-Folic Acid Plus D Chewable Wafers).

Contraindications: Calcium-Folic Acid Plus D Chewable Wafers are contraindicated in patients with hypersensitivity to any of its components. Calcium and vitamin D supplementation is contraindicated in those with hypercalcemia or conditions that may lead to hypercalcemia and those who form calcium containing stones are generally advised not to take supplemental calcium. Concomitant use of iron and calcium may inhibit the absorption of iron. Concomitant use of quinolones or tetracyclines with calcium may decrease the absorption of these medications. Folic acid is contraindicated in patients with

untreated and uncomplicated pernicious anemia, and in those with anaphylactic sensitivity to folic acid. The use of folic acid doses above 1 milligram/day may precipitate or exacerbate the neurological damage of vitamin B₁₂ deficiency. High doses of folic acid may result in decreased serum levels of the anticonvulsant drugs; carbamazepine, fosphenytoin, phenytoin, phenobarbital and valproic acid.

Precautions: Folic acid, especially in doses above 0.1 mg daily, may obscure pernicious anemia, in that hematologic remission may occur while neurological manifestations remain progressive.

Drug Interactions: As little as 5 mg of pyridoxine (vitamin B₆) daily can decrease the efficacy of levodopa. Therefore, Calcium-Folic Acid Plus D Chewable Wafers are not recommended for patients undergoing such therapy.

Information for Patients: Calcium-Folic Acid Plus D Chewable Wafers are medical food for use only under the direction and supervision of a licensed physician. Total intakes of greater than 2,000 mg of calcium provide no added benefit to bone health.

Pregnancy: Shall only be administered under the supervision of a physician.

Pediatric: Not recommended for pediatric use.

Adverse Reactions: Adverse reactions have been reported with specific vitamins and minerals, but generally at levels substantially higher than those in Calcium-Folic Acid Plus D Chewable Wafers. However, allergic and/or idiosyncratic reactions to vitamins even at lower potencies or any ingredient are possible.

Warning: Keep this and all medications out of the reach of children.

Dosage and Administration: Chew one wafer twice daily or as prescribed by a physician.

How Supplied: Brown-mottled, round shaped wafer, debossed on scored side with “BP 706”, plain on the other side. Calcium-Folic Acid Plus D Chewable Wafers are supplied in bottles of 60 wafers (42192-706-60). Store at room temperature, 15° - 30°C (59° - 86°F). Protect from light and moisture. The listed product number is not a National Drug Code, but has merely been formatted to comply with industry practice standard for pharmacy and insurance computer systems.

All prescription substitutions and/or recommendations using this product shall be made subject to state and federal statutes as applicable. **Please note: this is not an Orange Book product and has not been subjected to FDA therapeutic equivalency or other equivalency testing. No representation is made as to generic status or bioequivalency.** Each person recommending a prescription substitution using this product shall make such recommendations based on each such person’s professional opinion and knowledge, upon evaluating the active ingredients, excipients, inactive ingredients and chemical information provided herein.

THESE STATEMENTS HAVE NOT BEEN EVALUATED BY THE FOOD AND DRUG ADMINISTRATION. THIS PRODUCT IS NOT INTENDED TO DIAGNOSE, TREAT, CURE OR PREVENT ANY DISEASE.

Manufactured for:

Acella Pharmaceuticals, LLC

Alpharetta, GA 30022

1-800-541-4802

Rev.0313

PRINCIPAL DISPLAY PANEL - 60 wafers

NDC 42192-706-60

Calcium-Folic Acid Plus D

Chewable Wafers

**Calcium Vitamin/Mineral
Dietary Supplement**

R_x Only 60 Wafers

**Acella
PHARMACEUTICALS, LLC**

SUPPLEMENT FACTS

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Other Ingredients: Fructose, Natural Cocoa Dutch Chocolate, Stearic Acid, Pladone, Natural Chocolate Flavor, Magnesium Stearate, Acacia Gum, Silicon Dioxide

42192-706-60

Calcium-Folic Acid Plus D

**Chewable Wafers
Calcium Vitamin/Mineral
Dietary Supplement**

R_x only 60 Wafers

Acella
PHARMACEUTICALS, LLC

Suggested Dosage: Chew one wafer twice daily or as directed by a physician.

Storage: Keep tightly closed in a dry place at room temperature 15° - 30°C (59° - 86°F).

KEEP OUT OF THE REACH OF CHILDREN.

Manufactured for:
Acella Pharmaceuticals, LLC
11675 Great Oaks Way
Alpharetta, GA 30022
1-800-541-4802

Peel Corner

CALCIUM FOLIC ACID PLUS D CHEWABLE

cholecalciferol, magnesium, boron, folic acid, pyridoxine, cyanocobalamin wafer

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:42192-706
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CARBONATE	1342 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	300 [iU]
MAGNESIUM (UNII: I38ZP9992A) (MAGNESIUM - UNII:I38ZP9992A)	MAGNESIUM	50 mg
BORON (UNII: N9E3X5056Q) (BORON - UNII:N9E3X5056Q)	BORON	250 ug
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
PYRIDOXINE (UNII: KV2JZ1BI6Z) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	10 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	125 ug

Inactive Ingredients

Ingredient Name	Strength
FRUCTOSE (UNII: 6YSS42VSEV)	
COCOA (UNII: D9108TZ9KG)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POVIDONE K29/32 (UNII: 390RMW2PEQ)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
ACACIA (UNII: 5C5403N26O)	

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
Product Characteristics				
Color	brown	Score	2 pieces	
Shape	ROUND	Size	25mm	
Flavor		Imprint Code	BP;706	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42192-706-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	03/20/2009	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
unapproved drug other			03/20/2009	

Labeler - Acella Pharmaceuticals, LLC (825380939)

Establishment			
Name	Address	ID/FEI	Business Operations
Acella Pharmaceuticals, LLC		825380939	manufacture(42192-706)

Revised: 3/2018

Acella Pharmaceuticals, LLC